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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/604,227

07/02/2003

Jeffrey Grossman

31132.164

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46333 7590 03/29/2007  
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EXAMINER

POUS, NATALIE R

ART UNIT

PAPER NUMBER

3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/29/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/604,227

Applicant(s)

GROSSMAN, JEFFREY

Examiner

Natalie Pous

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-26 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-26 and 28-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 3/22/04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Arguments***

The indicated allowability of claims 1 and 3-23 is withdrawn in view of the newly discovered reference(s) to Heintzeman (US 6375395). Rejections based on the newly cited reference(s) follow.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 recites the limitation "the insertion device" in line 1. There is insufficient antecedent basis for this limitation in the claim. It is noted that claim 1 recites "an insertion device trajectory system *for use with* an insertion device," and thus does not positively claim the insertion device. Claim 10 is further rejected as being dependent from rejected claim 9.

Claims 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 18 recites the limitation "the insertion device" in line 6. There is insufficient antecedent basis for this limitation in the claim. Claims 19-21 are further rejected as being dependent from rejected claim 18.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 4, 6-9, 11, 12, 13, 15, 16, 22, 24-26, 29 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Heintzeman (US 6375395).

Regarding Claim 1, Heintzeman teaches an insertion device trajectory system capable of use with an insertion device of treating a patient, comprising:

An energy source (112) for producing an energy path (113) in a direction away from the patient (Column 1, proximate lines 29-34); an indication surface for indicating a trajectory of the energy path, thereby indicating any trajectory correction required for the

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insertion device (Column 1, proximate lines 29-34); and a mechanism (101) by which the energy source can be attached to the insertion device.

Regarding Claim 3, Heintzeman teaches the insertion device trajectory system of claim 1, further comprising: A reflecting element configured to reflect the energy path towards the indication surface (it is noted that a laser energy source inherently comprises reflecting elements)

Regarding Claim 4, Heintzeman teaches the insertion device trajectory system of claim 1, wherein the energy source comprises a light source (112).

Regarding Claim 6, Heintzeman teaches the insertion device trajectory system of claim 4 wherein the energy path (113) comprises a directed light, and wherein the attachment mechanism is adapted to direct the light towards a reflecting element (it is noted that a laser energy source inherently comprises reflecting elements)

Regarding Claim 7, Heintzeman teaches the insertion device trajectory system of claim 6 wherein the indication surface is positioned so that the light directed towards the reflecting element is visibly identifiable on the indication surface (Column 1, proximate lines 29-34)

Regarding Claim 8, Heintzeman teaches the insertion device trajectory system of claim 1, wherein the energy source is permanently secured to the insertion device by the attachment mechanism (it is noted that so long as a user doesn't remove the attachment mechanism from the device, the energy source is permanently secured to the insertion device).

Regarding Claim 9, Heintzeman teaches the insertion device trajectory system of claim 1, wherein the insertion device comprises a workpiece attached to a distal end of the insertion device, and wherein the attachment mechanism is configured so that the energy path from the energy source is coaxial with the workpiece (Column 3, proximate lines 15-22)

Regarding Claim 11, Heintzeman teaches the insertion device trajectory system of claim 1, further comprising: a visual indicator for indicating a trajectory for indicating a trajectory of the energy path (Column 1, proximate lines 29-34).

Regarding Claim 12, Heintzeman teaches the insertion device trajectory system of claim 6, wherein the reflective element comprises a reflective radiolucent material material (it is noted that the reflective element of a laser is inherently radiolucent).

Regarding Claim 13, Heintzeman teaches an insertion device trajectory system capable of use with an insertion device of treating a patient, comprising:  
An energy source (112) located on the instrument, wherein the energy source produces an energy path (113) in a direction away from the patient (Column 1, proximate lines 29-34); a reflecting element for reflecting the energy path (it is noted that a laser energy source inherently comprises reflecting elements for reflecting the energy source), a surface for indicating the proximity of the reflected energy path to the energy source to indicate any alignment correction required for the instrument patient (Column 1, proximate lines 29-34).

Regarding Claim 14, Heintzeman teaches an insertion device trajectory system of claim 13, wherein the surface is capable of being located adjacent the energy source,

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it is noted that since the surface is movable, it is capable of being placed adjacent the energy source.

Regarding Claim 15, Heintzeman teaches an insertion device trajectory system of claim 13, wherein the reflecting element comprise a reflective radiolucent material (it is noted that the reflective element of a laser is inherently radiolucent).

Regarding Claim 16, Heintzeman teaches the insertion device trajectory system of claim 13, wherein the energy source comprises a light source (112).

Regarding Claim 22, Heintzeman teaches an insertion device trajectory system capable of use with an insertion device of treating a patient, comprising:

An instrument (100) having a working end and an opposite proximal end; an energy source (112) adapted to selectively engage a portion of the instrument and for producing an energy path (113) in a direction away from the working end (Column 1, proximate lines 29-34); a surface for indicating the trajectory of the energy path, the trajectory of the energy path correlating to a trajectory of the instrument (Column 1, proximate lines 29-34); and a reflecting element configured to reflect the energy path towards the surface (it is noted that a laser energy source inherently comprises reflecting elements for reflecting the energy source).

Regarding Claim 24, Heintzeman teaches the system of claim 22, wherein the working end includes a cutting portion (it is noted that a drill bit is a cutting portion)

Regarding Claim 25, Heintzeman teaches the system of claim 22, further including a longitudinal axis (L) extending at least partially between the working end and the proximal end.

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Regarding Claim 26, Heintzeman teaches the system of claim 25, wherein the energy source is adapted to produce an energy path substantially parallel to the longitudinal axis (fig. 1)

Regarding Claim 29, Heintzeman teaches the system of claim 22, wherein the energy source (112) is a light source.

Regarding Claim 30, Heintzeman teaches the system of claim 29, wherein the energy source is adapted to selectively engage the proximal end of the instrument (fig. 6).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heintzeman in view of Pirtle (US 3628523). Heintzeman discloses all limitations of



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dependent claims 1, 9 and 13 as disclosed above but does not disclose that the work piece be a percutaneous needle. Heintzeman does however disclose that the guiding device is detachably mountable in a variety of ways on any suitable instruments. Pirtle discloses a percutaneous needle (Column 1, proximate lines 55-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Heintzeman with a percutaneous needle as taught by Pirtle in order to fulfill the devices capability of use on any tool.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heintzeman in view of Karram et al. (US 6428180). Heintzeman teaches all limitations of preceding dependent claim 1, but fails to teach wherein the energy source comprises a LED. Karram teaches a device for producing a directed energy source, wherein the energy source comprises a LED because it provides advantages such as small size, high efficiency, and low operating temperature and heat release. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device Heintzeman with an LED as taught by Karram in order to provide an energy source with a small size, high efficiency, and low operating temperature and heat release.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP  
3/27/07

  
**ANH TUAN T. NGUYEN**  
**SUPERVISORY PATENT EXAMINER**  
